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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,827	10/20/2004	Hartmut Klocke	KLOCKE2	8558
1444 7590 01/22/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303				
EXAMINER				
ALEXANDER, LYLE				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
01/22/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,827

Applicant(s)

KLOCKE, HARTMUT

Examiner

Lyle A. Alexander

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-20, 23-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20, 23-31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

In light of the 11/6/08 amendments, a further search was made and new a reference has been found.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-19, 23-26, 28-31, 33, 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steinbrink (USP 4,078,892).

Steinbrink teach a kit for the determination of bilirubin in blood. Column 2 lines 6+ teach the kit(10) comprises flexible walled, hermetically sealed reagent containers(14) that are packaged in a kit so that elements are conveniently available when needed. Hub(34) on the containers(14) is pierced by pipette(28) and permits transfer of the sample into the container(14). The hub(34) has also been read on the claimed "break away tip" and "adhesive film covering said inlet." Column 4 lines 43-51 teach the containers(14) have flexible walls(18) and are constructed from plastic materials, such as polyethylene or polypropylene. Further, capsule(20) contain reagent solution(22) and is within container(14). Figure 1 shows there are a series of contains to make colorimetric comparison and has been read on the claimed "information-carrying medium ...". The Office has read the claimed "*reaction chamber*" on the taught **container(14)**; the claimed "*inlet*" on the taught **hub(34)** and the claimed "*indicator chamber*" on the taught **capsule(20)**.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20, 27, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinbrink.

See Steinbrink *supra*.

Steinbrink are silent to the claimed litmus test strip of claim 20, the indicator or reaction in the form of a tablet of claim 27 and the at least two reaction chambers and/or two indicator chambers of claims 34 and 36.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The choice of an indicator is a result effective variable having the well known and expected results of detecting the analyte of interest. Also, the physical state of an indicator or reaction is a result effective variable providing the well known and expected results of indication. Finally, the number of reaction chambers and/or indicator chambers is a result effective variable based upon the scale of analysis desired.

Litmus test strips are notoriously well known in the art for testing the pH of a solution and is advantageous because it is inexpensive and widely available. It would have been within the skill of the art to modify Steinbrink and use a litmus paper test strip to test the pH of the test solution to gain the above advantages and as optimization of a result effective variable.

It is notoriously well known in the art to provide an indicator or reactant in a dry state in the form of a tablet to gain the advantages of less weight for shipping, easier handling of the indicator or reagent in the form of a tablet and a longer shelf life. It would have been within the skill of the art to modify Steinbrink and provide the indicator or reactant in the form of a dry, tablet to gain the above advantages and as optimization of a result effective variable.

It is well known in the art to provide multiple chambers in a device so that plural samples and/or test can be conducted simultaneously which will shorten the time required for analysis. It would have been within the skill of the art to further modify Steinbrink and provide at least two reaction chambers and/or two indicator chambers to gain the above advantages and as optimization of a result effective variable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1797

/Lyle A Alexander/
Primary Examiner, Art Unit 1797